## REMARKS/ARGUMENTS

Status of the Claims

Claims 1-28 and 30-78 are pending in the present application. Reexamination and reconsideration are respectfully requested in view of the following remarks.

The Objection to the Specification Should Be Withdrawn

The specification has been objected to on the grounds that it contains a hyperlink on line 17 of page 10. This hyperlink has been removed, thereby obviating the objection.

The Rejection of the Claims under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 1-78 have been rejected under 35 U.S.C. § 112, second paragraph, on the grounds that the phrase "biologically active" is indefinite. Applicants note that claim 29 was previously canceled in Applicants' Amendment filed December 29, 2003, rendering the rejection of this claim moot. The rejection of claims 1-28 and 30-78 is respectfully traversed for the reasons described below.

According to the *Manual of Patent Examining Procedure*, the test for the definiteness of a patent claim is "whether 'those skilled in the art would understand what is claimed when the claim is read in light of the specification.'" *Manual of Patent Examining Procedure* § 2173.02 (8th ed. Revision No. 1 Feb. 2003), citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). Claims 1-28 and 30-78 meet this standard. The specification states on lines 11-12 of page 11 that biologically active variants of IFN-$\beta$ retain IFN-$\beta$ activities, particularly the ability to bind to IFN-$\beta$ receptors. The specification also describes assays that may be used to determine whether IFN-$\beta$ variants are biologically active; see lines 17-23 of page 11. Thus, the specification describes the biological activity of IFN-$\beta$ and provides assays for measuring this activity. Therefore, one skilled in the art reading claims 1-28 and 30-78 in light of the specification would understand the scope of these claims.

In view of the above arguments and amendments, all grounds for rejection under 35 U.S.C. § 112, second paragraph, have been overcome. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

The Rejection of the Claims under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

Claims 1-78 have been rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not enable the production of all forms of highly purified mannitol. Applicants note that claim 29 was previously canceled in Applicants' Amendment filed December 29, 2003, rendering the rejection of this claim moot. The rejection of claims 1-28 and 30-78 is respectfully traversed for the reasons described below.

As the Examiner correctly notes in the Office Action, the use of highly purified mannitol having a low level of reducing activity is a key feature of the present invention. The Examiner argues that the specification must be enabling for the production of *all* forms of highly purified mannitol meeting the limitations of the claims. However, the Federal Circuit has held "[t]he enablement requirement is met if the description enables *any* mode of making and using the claimed invention." *Engel Industries Inc. v. The Lockformer Co.*, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991), emphasis added. Claims 1-28 and 30-78 meet this standard because the specification provides sufficient guidance to enable one of skill in the art to make highly purified mannitol having a low level of reducing activity. See, for example, line 29 of page 21 through line 21 of page 22, which describe methods of preparing highly purified mannitol by methanol extraction, or by methanol extraction, carbon treatment, ultrafiltration, and recrystallization. Figure 17 shows that these methods produce highly purified mannitol having a reducing activity that meets the definition of highly purified mannitol set forth on lines 24-25 of page 5 of the specification. Accordingly, claims 1-28 and 30-78 meet the enablement requirement set forth in *Engel*.

The Federal Circuit cases *Johns Hopkins Univ. v. Cellpro, Inc.*, 47 USPQ2d 1705 (Fed. Cir. 1998) and *Durel Corp. v. Osram Sylvania Inc.* 59 USPQ2d 1238 (Fed. Cir. 2001) also demonstrate that the specification need only teach one mode of making and using the claimed invention to satisfy the enablement requirement. In *Johns Hopkins*, one issue before the court was whether claims directed to anti-My-10 antibodies failed to meet the enablement requirement

when some of the methods described in the specification for producing the antibody were inoperative. The court held the claims would be invalid for lack of enablement only if *all* of the disclosed methods for producing the antibodies were inoperative. *Johns Hopkins*, 47 USPQ2d at 1719, citing *Engel Industries Inc. v. The Lockformer Co.*, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991).

In *Durel*, the claims at issue were directed to coatings comprising electroluminescent phosphor particles encapsulated in a metal oxide coating. Sylvania argued that Durel's claims were not enabled because the specification listed a number of possible precursors for the coating but did not provide methods of making the claimed coating from each of these precursors. However, the Federal Circuit disagreed, stating, "[i]f the disclosure enables a person of ordinary skill in the art to make a particular metal oxide coating from *at least one* of the suggested precursors, the enablement requirement is satisfied." *Durel*, 59 USPQ2d at 1244, emphasis added.

In summary, claims 1-28 and 30-78 meet the enablement standard set forth by the Federal Circuit in *Engel*, *Johns Hopkins*, and *Durel*, because the specification enables one of skill in the art to make and use the highly purified mannitol recited in these claims. Accordingly, all grounds for rejection under 35 U.S.C. § 112, first paragraph, have been overcome. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

## CONCLUSION

It is believed that all the rejections have been obviated or overcome and the claims are in condition for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned agent.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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